

MAILED

MAY 23 1996

PAT.&T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION.

This opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 20

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

*Ex parte* HAROLD C. WARREN, NORBERT S. NORKUS  
and MARGARET J. SMITH-LEWIS

Appeal No. 94-1091  
Application 07/546,980<sup>1</sup>

ON BRIEF

Before JOHN D. SMITH, TURNER, and WEIFFENBACH, *Administrative Patent Judges*.

JOHN D. SMITH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 1 through 5 and 22 through 25.

Claim 1 is representative and is reproduced below:

<sup>1</sup> Application for patent filed July 2, 1990, which is, according to appellants, a division of Application 07/155,441, filed February 12, 1988, now U.S. Patent 4,965,191.

Appeal No. 94-1091  
Application 07/546,980

1. An aqueous wash solution consisting essentially of a buffer to maintain its pH at from about 5 to about 9 and at least about 1.5 weight percent of a first water-soluble salt comprising a lower alcohol sulfate anion having from 6 to 10 carbon atoms and an alkali metal or ammonium cation, said solution having an ionic strength of from about 0.1 to about 0.5, said ionic strength being provided by either said buffer or a second water-soluble salt present in a concentration sufficient to provide said ionic strength, said second water-soluble salt having an alkali metal, ammonium or alkaline earth metal cation.

The references of record relied upon by the examiner are:

Thomson	4,816,440	Mar. 28,
1989		

Maniatis et al. (Maniatis), Molecular Cloning, A Laboratory Manual, 1982, pp. 191 and 445-447.

The appealed claims stand rejected under 35 USC § 103 as unpatentable over Thomson in view of Maniatis.

We reverse.

The subject matter on appeal is directed to a wash solution which is particularly useful as a part of a pregnancy test kit for separating uncomplexed materials (unwanted background species) from a receptor bound ligand (i.e., human chorionic gonadotropin hormone) which unwanted background species would otherwise reduce the assay sensitivity. As evident from claim 1 above, the wash solution requires a specific concentration of a salt of a lower alcohol sulfate (e.g., sodium decyl sulfate), a pH buffer, and a specific ionic strength.

As evidence of obviousness, the examiner principally relies on Thomson. This reference discloses a complex multi-step process for

Appeal No. 94-1091  
Application 07/546,980

purification of proteins such as interferons (IFNs) and natural human factor (IL-2) involving solubilization of cellular material containing the proteins using, *inter alia*, sodium decyl sulfate or sodium dodecyl sulfate (SDS)<sup>2</sup>, as a solubilizing agent. See column 12, lines 35 and 36 of Thomson. As an incidental step of the complex process of Thomson, a concentrate of the desired protein may be washed, and for this purpose, Thomson discloses an aqueous washing solution made up of a pH buffer (sodium phosphate) containing 0.1% sodium dodecyl sulfate (SDS). See Thomson at column 15, lines 57 through 61.

The examiner suggests that it would have been obvious to a person of ordinary skill in the art to modify the Thomson washing solution by using reagents such as sodium decyl sulfate disclosed as useful for solubilizing the desired proteins. Like appellants, we disagree. A careful review of Thomson reveals that the solubilizing solution and the washing solution are not the same, nor are they used for equivalent purposes. To equate the two solutions, as the examiner has done here, and interchange the components without a specific teaching of the reference is improper and manifests the legally impermissible use of hindsight in the formulation of the examiner's rejection. Moreover, even if one of ordinary skill in the art considered sodium decyl sulfate as

---

<sup>2</sup> SDS is not covered by the claimed invention which is limited to salts comprising a lower alcohol sulfate anion having from 6 to 10 carbon atoms.

Appeal No. 94-1091  
Application 07/546,980

equivalent to the preferred sodium dodecyl sulfate as a surfactant detergent in Thomson's washing solution, there still remains no motivation for adjusting the ionic strength of Thomson's washing solution. As expressly noted by appellants, adjustment of the ionic strength of the solubilizing solution of Thomson is effected for the purpose of enabling phase separation after an organic extraction process. Specifically see Thomson at column 12, lines 55 through 61.

Since the disclosures in the relied upon secondary reference to Maniatis do not remedy the basic deficiencies in the examiner's stated rejection based principally on Thomson, it is clear that the examiner has failed to establish a *prima facie* case of obviousness for the claimed subject matter on appeal. Therefore, we find it unnecessary to review the asserted evidence of nonobviousness with respect to the crystallization properties provided by the claimed washing solution.

Appeal No. 94-1091  
Application 07/546,980

The decision of the examiner, accordingly, is reversed.

**REVERSED**

JOHN D. SMITH  
Administrative Patent Judge

Vincent D. Turner  
VINCENT D. TURNER  
Administrative Patent Judge

BOARD OF PATENT  
APPEALS AND  
INTERFERENCES

CAMERON WEIFFENBACH  
Administrative Patent Judge

Appeal No. 94-1091  
Application 07/546,980

Audley A. Ciamparzero, Jr.  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003